Centralising remote data collection for patients with Motor Neuron Disease (MND): Lessons and considerations from the OptiCALS trial.

Shamila Ditta, Gemma Hackney, Elaine Scott, David White,Christopher McDermott, on behalf of the HighCALS group

The OptiCALS trial demonstrated that transitioning to a centralised remote data collection model is a feasible and accessible way to conduct clinical trials for patients with MND, though it requires careful consideration, regarding outcome measures, but can promote patient inclusion in MND research.

Introduction

The OptiCALS randomised controlled trial evaluates a dietary and behavioural intervention, designed to provide a daily personalised calorie target to increase or maintain BMI, correcting energy deficiencies, and potentially slowing disease progression in patients with MND[1].Originally scheduled for 2020, the trial faced significant hurdles due to the COVID-19 pandemic and overstretched NHS resources. To ensure continuity for this vulnerable population, the Sheffield Clinical Trials Unit (CTRU) transitioned to a centralised, remote data collection model.

Clinical outcomes: ALSFRS-R, limb girth and spirometry.



Approach

The CTRU maintained comprehensive oversight, coordinating and administering all remote data collection assessments. Participants received the intervention (delivered by the clinical site) or control (usual care) over a 12-month period with outcome assessments scheduled at Baseline, 1,3,6,9,and 12-months. Non-clinical CTRU research assistants underwent training to administer clinical outcomes, including the ALSFRS-R[2], spirometry, limb girth and questionnaires for example, the WHOQOL-BREF.[3] Outcome sessions were all conducted via remote video-conferencing. To ensure digital inclusion, tablets were provided to participants unable to access necessary technology.The CTRU's role in the data collection provided an opportunity to reflect on how remote assessments can be implemented across the broader clinical trial landscape.

Observations & Impact

Centralising assessments yielded several key insights:

- **Accessibility:** Remote delivery significantly reduced geospatial barriers and the physical burden of travel for a functionally declining population. This approach may facilitate lower attrition rates and encourage broader research inclusion.
- **Data Quality:** Utilising a small, dedicated central team potentially improved inter-rater reliability. However, remote physical measures required participant and carer ability, so careful consideration should be given to outcome choice.
- **Workforce:** Non-clinical staff successfully navigated sensitive interactions with vulnerable participants, though this required robust support systems, where staff were able to discuss any concerns.

Recommendations

We delivered an RCT which required use of a variety of technologies (e.g. video-conferencing, smart phone apps) to a vulnerable population group remotely, with good levels of data accrual. The trial demonstrates that RCTs involving remote data collection are feasible for vulnerable cohorts. Future studies should consider:

1. **Flexible Inclusion:** Offer remote assessments as a standard option to encourage research participation of patients with MND.
2. **Participant Outcome Measures:**.Consider an initial in person baseline visit to train participants on physical measurement techniques.
3. **Administrative Timescales:** Processing and maintaining research permissions is time-consuming for central and NHS staff.

References

1.Peace A, White DA, Hackney G, Bradburn M, Norman P, White S, et al. Randomised controlled trial with parallel process evaluation and health economic analysis to evaluate a nutritional management intervention, OptiCALS, for patients with amyotrophic lateral sclerosis: study protocol. PMID: 40436457

2. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). *J Neurol Sci* 1999; 169(1-2): 13-21. DOI:10.1016/S0022-510X(99)00210-5

3. Young CA, Mills R, Al-Chalabi A, Burke G, Siddharthan C, Dick DJ, Ealing J, Hanemann CO, Harrower T, McDermott CJ, Majeed T, Pinto A, Talbot K, Walsh J, Williams TL, Tennant A & TONiC study group. Measuring quality of life in ALS/MND: validation of the WHOQOL-BREF. *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration* 2020; DOI: 10.1080/21678421.2020.1752244.

Acknowledgments

This project is funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1016-20006) and supported by the NIHR Sheffield Biomedical Research Centre. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

We would like to thank the staff and participants from sites for their valuable contributions.

We also thank the wider HighCALS research group for their support and collaboration.

University of Sheffield | Clinical Trials Research Unit
School of Health & Related Research

Sheffield Teaching Hospitals NHS Foundation Trust

UK Registered Clinical Trials Unit Network

Funded by NIHR | National Institute for Health and Care Research

OptiCALS

Email us:
opticals@sheffield.ac.uk